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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,156	12/07/2001	Douglas James Hilton	11268A	7385

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Scully, Scott, Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER
ULM, JOHN D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,156	HILTON ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11 and 15-29* is/are pending in the application.

4a) Of the above claim(s) *15-19,21,22,25-27 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11,20,23,24 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/043,816.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 6 to 11 and 15 to 29 are pending in the instant application.

2) Claims15 to 19, 21, 22, 25 to 27 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15. The traversal is on the ground(s) that a restriction requirement is only proper when inventions are "independent and distinct". This is not found persuasive because this premise is completely in conflict with current patent practice as explained in M.P.E.P. 803 as follows.

803 Restriction - When Proper [R - 2]

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(j)) or distinct>(< MPEP § 806.05 - § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

(2) There must be a serious burden on the examiner if restriction is not required (see MPEP § 803.02 § 806.04(a) - (j), § 808.01(a) and § 808.02).

GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the requirement in most cases.

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

If there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required, In re Lee,199 USPQ 108 (Deputy Asst. Comm'r. for Pats 1978).

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows **by** appropriate explanation either **separate classification**, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush - type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus - species, see MPEP § 806.04(a) - (j) and MPEP § 808.01(a).

Because Applicant's traversal is based upon a premise which is directly contrary to current patent practice, as explained above, and an initial search burden was shown by separate classification of the different inventions the requirement is still deemed proper and is therefore made FINAL.

3) Claims 23 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4) Claims 6 to 11, 20, 23 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention .as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate is scope with the claims. The only manner of employing a "haemopoietin receptor" of the instant invention in a manner meeting the "useful" requirement of 35 U.S.C. 101 is based upon Applicant's disclosure that the "haemopoietin receptor" that is described in the instant specification functions as a leptin receptor. No other ligand is disclosed or suggested for this receptor protein. The instant claims essentially encompass any protein capable of functioning as a leptin receptor and which can be encoded by a nucleic acid which hybridizes to any one or more of the nucleic acids recited therein under moderately stringent conditions. It is noted that the vast majority of nucleic acids which could hybridize to the referenced polynucleotides under moderately stringent conditions could not be expected to encode a functional receptor for leptin or any other ligand. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The only leptin receptor which is described in the instant specification "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" it comprises the entire amino acid sequence that is presented in SEQ ID NO:13 of the instant application. The instant specification does not provide a general structural formula of the genus of proteins encompassed by the term "haemopoietin receptor" nor does it disclose how to use an isolated nucleic acid encoding a haemopoietin receptor of the instant invention

which does not function as a leptin receptor. Because the probes and hybridization conditions recited in these claims can only define a very small portion of the coding region needed by a nucleic acid to encoded a functional leptin receptor, these claims place few structural limitations on the recited nucleic acid and those structural limitations which are defined by the hybridization limitations of these claims are insufficient to meet the functional limitation of encoding a "haemopoietin receptor". Because the hybridization limitations of these claims essentially place almost no structural limitation on the claimed nucleic acids or any proteins encoded thereby, these claims are almost equivalent to single means claims, since they encompass recombinant haemopoietin receptor irrespective of the structure of that receptor. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a)

The text beginning in line16 on page 8 of the instant specification expressly indicates that the instant claims are intended to encompass any reombinant

haemopoietin receptor of mammalian or avian origin so long as that nucleic acid meets the hybridization limitations of the claims. The instant specification, however, only describes a single species of the claimed nucleic acid and a single species of haemopoietin receptor. *In re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

> " It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.21 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary."

The very broad genus of recombinant haemopoietin receptors encompassed by the instant claims is not supported by the disclosure of that single naturally occurring species of recombinant haemopoietin receptor that is described in the instant specification.

The text beginning in line 6 on page 9 of the instant specification indicates that the instant claims are intended to encompass "fragments, parts, portions, mutants, homologues and "analogues" of the single protein disclosed therein as well as derivatives which "include single or multiple amino acid substitutions, deletions and/or additions". *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

The instant specification does not identify those amino acid residues in the amino acid sequence presented in SEQ ID NO:13 of the instant application which are critical to the structural and functional integrity of a haemopoietin receptor and those residues which are expendable. The instant specification does not identify even a single structurally and functionally related protein in the prior art for which this information is known and could be applied to SEQ ID NO:13 by analogy. Whereas the instant claims encompass an extraordinarily large number of recombinant, non-naturally occurring haemopoietin receptors having an almost unlimited number of modifications relative to that single, naturally occurring protein which is described in the instant specification, there is not even a single working example of a modified haemopoietin receptor. In the complete absence of guidance or working examples an artisan can not make a recombinant

haemopoietin receptor whose amino acid sequence differs from that of SEQ ID NO:13 by even a single amino acid and predict "by resort to known scientific law" if the modified protein will function as a leptin receptor. And if a haemopoietin receptor does not function as a leptin receptor, the instant specification does not disclose how to use it.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 6 to 11, 20, 23, 24 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite because the metes and bounds of the limitation "derivative" are undeterminable, particularly in view of the definition of this term that is provided on page 9 of the instant specification. Further, it is unclear if the "derivative thereof" is also supposed to function as a "haemopoietin receptor" and, if it is, then the inclusion of this term is confusing because the "derivative" is already encompassed by the term "haemopoietin receptor".

6) Claims 6 to 11, 20 and 23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Snodgrass et al. patent (5,763,211). The coding region of the polynucleotide presented in SEQ ID NO:35 of the Snodgrass et al. patent is 99.65% identical to the coding region of SEQ ID NO:12 of the instant application and the amino acid sequence presented in SEQ ID NO:36 of the Snodgrass et al. patent is 96.7%

identical to the amino acid sequence presented in SEQ ID NO:13 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800